William P. Deni, Jr.
J. Brugh Lower
GIBBONS P.C.
One Gateway Center
Newark, New Jersey 07102
Tel: (973) 596-4500
Fax: (973) 596-0545
Attorneys for Plaintiffs

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

BAUSCH HEALTH COMPANIES INC.; SALIX PHARMACEUTICALS, INC.; PROGENICS PHARMACEUTICALS, INC.; and WYETH LLC, Plaintiffs, v. GLAND PHARMA LIMITED, Defendant.	Civil Action No. 22-939 *Document Electronically Filed*

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Bausch Health Companies Inc. ("Bausch"), Salix Pharmaceuticals, Inc. ("Salix"), Progenics Pharmaceuticals, Inc. ("Progenics"), and Wyeth LLC (collectively, "Plaintiffs") by way of Complaint against Defendant Gland Pharma Limited ("Gland") allege as follows:

THE PARTIES

1. Plaintiff Bausch is a company organized and existing under the laws of Canada, having its United States headquarters at 400 Somerset Corporate Boulevard, Bridgewater, New Jersey 08807.

2. Plaintiff Salix is a corporation organized and existing under the laws of California, having its corporate headquarters at 400 Somerset Corporate Boulevard, Bridgewater, New Jersey

08807. Salix is the registered holder of approved New Drug Application ("NDA") No. 021964, which covers subcutaneous Relistor® solution.

3. Plaintiff Progenics, which is a Lantheus Company, is a corporation organized and existing under the laws of Delaware, having its principal place of business at 331 Treble Cove Road, North Billerica, Massachusetts 01862.

4. Plaintiff Wyeth LLC, formerly Wyeth, is a Delaware limited liability company, having places of business at 235 East 42nd Street, New York, NY 10017.

5. Upon information and belief, Gland is a company organized and existing under the laws of India, having a place of business at Survey No. 143-148, 150 & 151 Near Gandimaisamma 'X' Roads D.P. Pally, Dundigal Gandimaisamma Mandal Medchal-Malkjgiri District, Hyderabad 500043, Telangana, India.

NATURE OF THE ACTION

6. This is an action for infringement of United States Patent Nos. 8,247,425 ("the '425 patent"); 8,420,663 ("the '663 patent"); 8,552,025 ("the '025 patent"); 8,822,490 ("the '490 patent"); 9,180,125 ("the '125 patent"); 9,492,445 ("the '445 patent"); 9,669,096 ("the '096 patent"); and 10,376,584 ("the '584 patent") arising under the United States patent laws, Title 35, United States Code, § 100 et seq., including 35 U.S.C. §§ 271 and 281, and for declaratory judgment of infringement under 28 U.S.C. §§ 2201 and 2202. This action relates to Gland's filing of an Abbreviated New Drug Application ("ANDA") under Section 505(j) of the Federal Food, Drug, and Cosmetic Act ("the Act"), 21 U.S.C. § 355(j), seeking U.S. Food and Drug Administration ("FDA") approval to market its generic methylnaltrexone bromide products for subcutaneous injection, 12 mg/0.6 mL single-use vials ("Gland's proposed generic methylnaltrexone vial product") and 12 mg/0.6 mL pre-filled syringes ("Gland's proposed generic

methylnaltrexone pre-filled syringe product") (collectively "Gland's generic methylnaltrexone injectable products").

JURISDICTION AND VENUE

7. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202.

8. Upon information and belief, this court has jurisdiction over Gland. Upon information and belief, Gland is in the business of manufacturing, marketing, importing, and selling pharmaceutical products, including generic drug products. Upon information and belief, Gland directly, or indirectly, manufactures, markets, and sells generic drug products throughout the United States and in this judicial district, and this judicial district is a likely destination for Gland's proposed generic methylnaltrexone injectable products. Upon information and belief, Gland has purposefully conducted and continues to conduct business in this judicial district.

9. Gland has taken the costly, significant step of applying to the FDA for approval to engage in future activities—including the marketing of its generic drugs—that will be purposefully directed at, upon information and belief, the State of New Jersey and elsewhere. Gland's ANDA filings constitute formal acts that reliably indicate plans to engage in marketing of the proposed generic drugs. Upon information and belief, Gland intends to direct sales of its drugs into New Jersey, among other places, once it has the requested FDA approval to market them. Upon information and belief, Gland will engage in marketing of its proposed generic methylnaltrexone injectable products in New Jersey upon approval of its ANDAs.

10. Upon information and belief, Gland has designated Andrew J. Miller, Esq. of Windels Marx Lane & Mittendorf, LLP located in New Jersey at One Giralda Farms, Suite 100, Madison, NJ 07940 as its U.S. agent authorized to accept service of process pursuant to 21 C.F.R.

§ 314.95(c)(9) with respect to Gland's ANDAs seeking FDA approval of its proposed generic methylnaltrexone injectable products.

11. Upon information and belief, Gland has previously submitted to the jurisdiction of this Court and has further previously availed itself of this Court by asserting counterclaims in at least the following actions: *Fresenius Kabi Deutschland GmbH et al v. Gland Pharma Limited*, No. 3:20-cv-12347 (D.N.J.) (Sept. 4, 2020); *Merck Sharp & Dohme B.V. et al v. Gland Pharma Limited*, No. 2:20-cv-02750 (D.N.J.) (Mar. 12, 2020); *Chiesi USA Inc. et al v. Gland Pharma Limited*, No. 2:19-cv-18565 (D.N.J.) (Sept. 30, 2019); *Medicure Int'l, Inc. v. Gland Pharma Limited*, No. 2:18-cv-16246 (D.N.J.) (Nov. 16, 2018).

12. Venue is proper in this district at least because Gland is a foreign entity that may be sued in any judicial district under 28 U.S.C. §§ 1391(c)(3) and 1400(b).

13. Upon information and belief, Gland has previously not contested venue in this district. *See e.g.*, *Fresenius Kabi Deutschland GmbH et al v. Gland Pharma Limited*, No. 3:20-cv-12347 (D.N.J.) (Sept. 4, 2020); *Merck Sharp & Dohme B.V. et al v. Gland Pharma Limited*, No. 2:20-cv-02750 (D.N.J.) (Mar. 12, 2020); *Chiesi USA Inc. et al v. Gland Pharma Limited*, No. 2:19-cv-18565 (D.N.J.) (Sept. 30, 2019); *Medicure Int'l, Inc. v. Gland Pharma Limited*, No. 2:18-cv-16246 (D.N.J.) (Nov. 16, 2018).

THE PATENTS IN SUIT

14. The U.S. Patent and Trademark Office ("PTO") issued the '425 patent on August 21, 2012. The '425 patent claims, *inter alia*, pre-filled syringes comprising liquid compositions of methylnaltrexone and methods of using the same. Plaintiffs hold all substantial rights in the '425 patent and have the right to sue for infringement thereof. A copy of the '425 patent is attached as Exhibit A.

15. The PTO issued the '663 patent on April 16, 2013. The '663 patent claims, *inter alia*, methods of using compositions of methylnaltrexone. Plaintiffs hold all substantial rights in the '663 patent and have the right to sue for infringement thereof. A copy of the '663 patent is attached as Exhibit B.

16. The PTO issued the '025 patent on October 8, 2013. The '025 patent claims, *inter alia*, pharmaceutical preparations of methylnaltrexone. Plaintiffs hold all substantial rights in the '025 patent and have the right to sue for infringement thereof. A copy of the '025 patent is attached as Exhibit C.

17. The PTO issued the '490 patent on September 2, 2014. The '490 patent claims, *inter alia*, packaged compositions comprising liquid compositions of methylnaltrexone and methods of using the same. Plaintiffs hold all substantial rights in the '490 patent and have the right to sue for infringement thereof. A copy of the '490 patent is attached as Exhibit D.

18. The PTO issued the '125 patent on November 10, 2015. The '125 patent claims, *inter alia*, compositions of methylnaltrexone and methods of using the same. Plaintiffs hold all substantial rights in the '125 patent and have the right to sue for infringement thereof. A copy of the '125 patent is attached as Exhibit E.

19. The PTO issued the '445 patent on November 15, 2016. The '445 patent claims, *inter alia*, compositions of methylnaltrexone and methods of using the same. Plaintiffs hold all substantial rights in the '445 patent and have the right to sue for infringement thereof. A copy of the '445 patent is attached hereto as Exhibit F.

20. The PTO issued the '096 patent on June 6, 2017. The '096 patent claims, *inter alia*, pharmaceutical preparations of methylnaltrexone. Plaintiffs hold all substantial rights in the '096

patent and have the right to sue for infringement thereof. A copy of the '096 patent is attached as Exhibit G.

21. The PTO issued the '584 patent on August 13, 2019. The '584 patent claims, *inter alia*, pharmaceutical preparations of methylnaltrexone and methods of using the same. Plaintiffs hold all substantial rights in the '584 patent and have the right to sue for infringement thereof. A copy of the '584 patent is attached as Exhibit H.

22. Salix is the holder of NDA No. 021964 for subcutaneous Relistor® solution. In conjunction with NDA No. 021964, the '425 patent, the '663 patent, the '025 patent, the '490 patent, the '125 patent, the '445 patent, the '096 patent, and the '584 patent are listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book").

23. Methylnaltrexone bromide for subcutaneous injection, 12 mg/0.6 mL single-use vials and 8 mg/0.4 mL and 12 mg/0.6 mL pre-filled syringes, are sold in the United States under the trademark Relistor®.

GLAND'S INFRINGING ANDA NO. 216836 SUBMISSION

24. Upon information and belief, Gland filed or caused to be filed with the FDA ANDA No. 216836, under section 505(j) of the Act and 21 U.S.C. § 355(j).

25. Upon information and belief, Gland's ANDA No. 216836 seeks FDA approval to engage in the commercial manufacture, use or sale in the United States of Gland's proposed generic methylnaltrexone vial product, intended to be a generic version of Relistor® 12 mg/0.6 mL single-use vials.

26. Plaintiffs received a letter from Gland dated January 8, 2022, purporting to be a Notice of Paragraph IV Certification for ANDA No. 216836 ("Gland's ANDA No. 216836 notice

letter") under Section 505(j)(2)(B)(ii) and (iv) of the Act, 21 U.S.C. § 355(j)(2)(B)(ii), (iv), and 21 C.F.R. § 314.95. Gland's notice letter was addressed to Salix.

27. Gland's ANDA No. 216836 notice letter alleges that Gland has submitted to the FDA ANDA No. 216836 seeking FDA approval to engage in the commercial manufacture, use or sale of Gland's proposed generic methylnaltrexone vial product, intended to be a generic version of Relistor® 12 mg/0.6 mL single-use vials.

28. Gland's ANDA No. 216836 notice letter states that Gland's ANDA No. 216836 contains the "required bioavailability or bioequivalence data or information with respect to methylnaltrexone bromide vials for injection containing 12 mg/0.6 mL," for Gland's proposed generic methylnaltrexone vial product.

29. Gland's ANDA No. 216836 notice letter, which is required by statute and regulation to provide a full and detailed explanation regarding any non-infringement defenses, does not allege non-infringement of any claim of the '025, '096, or '584 patents, and fails to provide any specific non-infringement allegations as to any claim of the '425, '663, '490, '125, or '445 patents.

30. Upon information and belief, ANDA No. 216836 seeks approval of Gland's proposed generic methylnaltrexone vial product that is the same, or substantially the same, as Relistor® 12 mg/0.6 mL single-use vials.

GLAND'S INFRINGING ANDA NO. 216965 SUBMISSION

31. Upon information and belief, Gland filed or caused to be filed with the FDA ANDA No. 216965, under section 505(j) of the Act and 21 U.S.C. § 355(j).

32. Upon information and belief, Gland's ANDA No. 216965 seeks FDA approval to engage in the commercial manufacture, use or sale in the United States of Gland's proposed

generic methylnaltrexone pre-filled syringe product, intended to be a generic version of Relistor® 12 mg/0.6 mL pre-filled syringes.

33. Plaintiffs received a letter from Gland dated January 21, 2022, purporting to be a Notice of Paragraph IV Certification for ANDA No. 216965 ("Gland's ANDA No. 216965 notice letter") under Section 505(j)(2)(B)(ii) and (iv) of the Act, 21 U.S.C. § 355(j)(2)(B)(ii), (iv), and 21 C.F.R. § 314.95. Gland's notice letter was addressed to Salix.

34. Gland's ANDA No. 216965 notice letter alleges that Gland has submitted to the FDA ANDA No. 216965 seeking FDA approval to engage in the commercial manufacture, use or sale of Gland's proposed generic methylnaltrexone pre-filled syringe product, intended to be a generic version of Relistor® 12 mg/0.6 mL pre-filled syringes.

35. Gland's ANDA No. 216965 notice letter states that Gland's ANDA No. 216965 contains the "required bioavailability or bioequivalence data or information with respect to methylnaltrexone bromide prefilled syringes for injection containing 12 mg/0.6 mL," for Gland's proposed generic methylnaltrexone pre-filled syringe product.

36. Gland's ANDA No. 216965 notice letter, which is required by statute and regulation to provide a full and detailed explanation regarding any non-infringement defenses, does not allege non-infringement of any claim of the '425, '663, '025, '490, '125, '445, '096, or '584 patents.

37. Upon information and belief, ANDA No. 216965 seeks approval of Gland's proposed generic methylnaltrexone pre-filled syringe product that is the same, or substantially the same, as Relistor® 12 mg/0.6 mL pre-filled syringes.

COUNT I AGAINST GLAND

Infringement of the ’425 Patent Under § 271(e)(2) (ANDA No. 216836)

38. Paragraphs 1-37 are incorporated herein as set forth above.

39. Under 35 U.S.C. § 271(e)(2), Gland has infringed at least one claim of the ’425 patent by submitting, or causing to be submitted to the FDA, ANDA No. 216836 seeking approval for the commercial marketing of Gland’s proposed generic methylnaltrexone vial product before the expiration date of the ’425 patent.

40. Upon information and belief, Gland’s proposed generic methylnaltrexone vial product will, if approved and marketed, infringe at least one claim of the ’425 patent.

41. Upon information and belief, Gland will, through the manufacture, use, import, offer for sale, and/or sale of Gland’s proposed generic methylnaltrexone vial product, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the ’425 patent.

42. If Gland’s marketing and sale of Gland’s proposed generic methylnaltrexone vial product prior to the expiration of the ’425 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

COUNT II AGAINST GLAND

Declaratory Judgment of Infringement of the ’425 Patent (ANDA No. 216836)

43. Paragraphs 1-42 are incorporated herein as set forth above.

44. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

45. There is an actual case or controversy such that the Court may entertain Plaintiffs’ request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

46. Gland has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Gland's proposed generic methylnaltrexone vial product before the expiration date of the '425 patent, including Gland's filing of ANDA No. 216836.

47. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Gland's proposed generic methylnaltrexone vial product will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '425 patent.

48. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Gland's proposed generic methylnaltrexone vial product will constitute infringement of at least one claim of the '425 patent.

COUNT III AGAINST GLAND

Infringement of the '663 Patent Under § 271(e)(2) (ANDA No. 216836)

49. Paragraphs 1-48 are incorporated herein as set forth above.

50. Under 35 U.S.C. § 271(e)(2), Gland has infringed at least one claim of the '663 patent by submitting, or causing to be submitted to the FDA, ANDA No. 216836 seeking approval for the commercial marketing of Gland's proposed generic methylnaltrexone vial product before the expiration date of the '663 patent.

51. Upon information and belief, Gland's proposed generic methylnaltrexone vial product will, if approved and marketed, infringe at least one claim of the '663 patent.

52. Upon information and belief, Gland will, through the manufacture, use, import, offer for sale, and/or sale of Gland's proposed generic methylnaltrexone vial product, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '663 patent.

53. If Gland's marketing and sale of Gland's proposed generic methylnaltrexone vial product prior to the expiration of the '663 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

COUNT IV AGAINST GLAND

Declaratory Judgment of Infringement of the '663 Patent (ANDA No. 216836)

54. Paragraphs 1-53 are incorporated herein as set forth above.

55. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

56. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

57. Gland has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Gland's proposed generic methylnaltrexone vial product before the expiration date of the '663 patent, including Gland's filing of ANDA No. 216836.

58. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Gland's proposed generic methylnaltrexone vial product will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '663 patent.

59. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Gland's proposed generic methylnaltrexone vial product will constitute infringement of at least one claim of the '663 patent.

COUNT V AGAINST GLAND

Infringement of the ’025 Patent Under § 271(e)(2) (ANDA No. 216836)

60. Paragraphs 1-59 are incorporated herein as set forth above.

61. Under 35 U.S.C. § 271(e)(2), Gland has infringed at least one claim of the ’025 patent by submitting, or causing to be submitted to the FDA, ANDA No. 216836 seeking approval for the commercial marketing of Gland’s proposed generic methylnaltrexone vial product before the expiration date of the ’025 patent.

62. Upon information and belief, Gland’s proposed generic methylnaltrexone vial product will, if approved and marketed, infringe at least one claim of the ’025 patent.

63. Upon information and belief, Gland will, through the manufacture, use, import, offer for sale, and/or sale of Gland’s proposed generic methylnaltrexone vial product, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the ’025 patent.

64. If Gland’s marketing and sale of Gland’s proposed generic methylnaltrexone vial product prior to the expiration of the ’025 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

COUNT VI AGAINST GLAND

Declaratory Judgment of Infringement of the ’025 Patent (ANDA No. 216836)

65. Paragraphs 1-64 are incorporated herein as set forth above.

66. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

67. There is an actual case or controversy such that the Court may entertain Plaintiffs’ request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

68. Gland has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Gland's proposed generic methylnaltrexone vial product before the expiration date of the '025 patent, including Gland's filing of ANDA No. 216836.

69. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Gland's proposed generic methylnaltrexone vial product will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '025 patent.

70. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Gland's proposed generic methylnaltrexone vial product will constitute infringement of at least one claim of the '025 patent.

COUNT VII AGAINST GLAND

Infringement of the '490 Patent Under § 271(e)(2) (ANDA No. 216836)

71. Paragraphs 1-70 are incorporated herein as set forth above.

72. Under 35 U.S.C. § 271(e)(2), Gland has infringed at least one claim of the '490 patent by submitting, or causing to be submitted to the FDA, ANDA No. 216836 seeking approval for the commercial marketing of Gland's proposed generic methylnaltrexone vial product before the expiration date of the '490 patent.

73. Upon information and belief, Gland's proposed generic methylnaltrexone vial product will, if approved and marketed, infringe at least one claim of the '490 patent.

74. Upon information and belief, Gland will, through the manufacture, use, import, offer for sale, and/or sale of Gland's proposed generic methylnaltrexone vial product, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '490 patent.

75. If Gland's marketing and sale of Gland's proposed generic methylnaltrexone vial product prior to the expiration of the '490 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

COUNT VIII AGAINST GLAND

Declaratory Judgment of Infringement of the '490 Patent (ANDA No. 216836)

76. Paragraphs 1-75 are incorporated herein as set forth above.

77. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

78. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

79. Gland has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Gland's proposed generic methylnaltrexone vial product before the expiration date of the '490 patent, including Gland's filing of ANDA No. 216836.

80. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Gland's proposed generic methylnaltrexone vial product will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '490 patent.

81. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Gland's proposed generic methylnaltrexone vial product will constitute infringement of at least one claim of the '490 patent.

COUNT IX AGAINST GLAND

Infringement of the '125 Patent Under § 271(e)(2) (ANDA No. 216836)

82. Paragraphs 1-81 are incorporated herein as set forth above.

83. Under 35 U.S.C. § 271(e)(2), Gland has infringed at least one claim of the '125 patent by submitting, or causing to be submitted to the FDA, ANDA No. 216836 seeking approval for the commercial marketing of Gland's proposed generic methylnaltrexone vial product before the expiration date of the '125 patent.

84. Upon information and belief, Gland's proposed generic methylnaltrexone vial product will, if approved and marketed, infringe at least one claim of the '125 patent.

85. Upon information and belief, Gland will, through the manufacture, use, import, offer for sale, and/or sale of Gland's proposed generic methylnaltrexone vial product, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '125 patent.

86. If Gland's marketing and sale of Gland's proposed generic methylnaltrexone vial product prior to the expiration of the '125 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

COUNT X FOR PATENT INFRINGEMENT

Declaratory Judgment of Infringement of the '125 Patent (ANDA No. 216836)

87. Paragraphs 1-86 are incorporated herein as set forth above.

88. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

89. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

90. Gland has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Gland's proposed generic methylnaltrexone vial product before the expiration date of the '125 patent, including Gland's filing of ANDA No. 216836.

91. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Gland's proposed generic methylnaltrexone vial product will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '125 patent.

92. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Gland's proposed generic methylnaltrexone vial product will constitute infringement of at least one claim of the '125 patent.

COUNT XI AGAINST GLAND

Infringement of the '445 Patent Under § 271(e)(2) (ANDA No. 216836)

93. Paragraphs 1-92 are incorporated herein as set forth above.

94. Under 35 U.S.C. § 271(e)(2), Gland has infringed at least one claim of the '445 patent by submitting, or causing to be submitted to the FDA, ANDA No. 216836 seeking approval for the commercial marketing of Gland's proposed generic methylnaltrexone vial product before the expiration date of the '445 patent.

95. Upon information and belief, Gland's proposed generic methylnaltrexone vial product will, if approved and marketed, infringe at least one claim of the '445 patent.

96. Upon information and belief, Gland will, through the manufacture, use, import, offer for sale, and/or sale of Gland's proposed generic methylnaltrexone vial product, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '445 patent.

97. If Gland's marketing and sale of Gland's proposed generic methylnaltrexone vial product prior to the expiration of the '445 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

COUNT XII AGAINST GLAND

Declaratory Judgment of Infringement of the '445 Patent (ANDA No. 216836)

98. Paragraphs 1-97 are incorporated herein as set forth above.

99. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

100. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

101. Gland has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Gland's proposed generic methylnaltrexone vial product before the expiration date of the '445 patent, including Gland's filing of ANDA No. 216836.

102. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Gland's proposed generic methylnaltrexone vial product will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '445 patent.

103. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Gland's proposed generic methylnaltrexone vial product will constitute infringement of at least one claim of the '445 patent.

COUNT XIII AGAINST GLAND

Infringement of the ’096 Patent Under § 271(e)(2) (ANDA No. 216836)

104. Paragraphs 1-103 are incorporated herein as set forth above.

105. Under 35 U.S.C. § 271(e)(2), Gland has infringed at least one claim of the ’096 patent by submitting, or causing to be submitted to the FDA, ANDA No. 216836 seeking approval for the commercial marketing of Gland’s proposed generic methylnaltrexone vial product before the expiration date of the ’096 patent.

106. Upon information and belief, Gland’s proposed generic methylnaltrexone vial product will, if approved and marketed, infringe at least one claim of the ’096 patent.

107. Upon information and belief, Gland will, through the manufacture, use, import, offer for sale, and/or sale of Gland’s proposed generic methylnaltrexone vial product, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the ’096 patent.

108. If Gland’s marketing and sale of Gland’s proposed generic methylnaltrexone vial product prior to the expiration of the ’096 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

COUNT XIV AGAINST GLAND

Declaratory Judgment of Infringement of the ’096 Patent (ANDA No. 216836)

109. Paragraphs 1-108 are incorporated herein as set forth above.

110. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

111. There is an actual case or controversy such that the Court may entertain Plaintiffs’ request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

112. Gland has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Gland's proposed generic methylnaltrexone vial product before the expiration date of the '096 patent, including Gland's filing of ANDA No. 216836.

113. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Gland's proposed generic methylnaltrexone vial product will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '096 patent.

114. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Gland's proposed generic methylnaltrexone vial product will constitute infringement of at least one claim of the '096 patent.

COUNT XV AGAINST GLAND

Infringement of the '584 Patent Under § 271(e)(2) (ANDA No. 216836)

115. Paragraphs 1-114 are incorporated herein as set forth above.

116. Under 35 U.S.C. § 271(e)(2), Gland has infringed at least one claim of the '584 patent by submitting, or causing to be submitted to the FDA, ANDA No. 216836 seeking approval for the commercial marketing of Gland's proposed generic methylnaltrexone vial product before the expiration date of the '584 patent.

117. Upon information and belief, Gland's proposed generic methylnaltrexone vial product will, if approved and marketed, infringe at least one claim of the '584 patent.

118. Upon information and belief, Gland will, through the manufacture, use, import, offer for sale, and/or sale of Gland's proposed generic methylnaltrexone vial product, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '584 patent.

119. If Gland's marketing and sale of Gland's proposed generic methylnaltrexone vial product prior to the expiration of the '584 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

COUNT XVI AGAINST GLAND

Declaratory Judgment of Infringement of the '584 Patent (ANDA No. 216836)

120. Paragraphs 1-119 are incorporated herein as set forth above.

121. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

122. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

123. Gland has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Gland's proposed generic methylnaltrexone vial product before the expiration date of the '584 patent, including Gland's filing of ANDA No. 216836.

124. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Gland's proposed generic methylnaltrexone vial product will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '584 patent.

125. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Gland's proposed generic methylnaltrexone vial product will constitute infringement of at least one claim of the '584 patent.

COUNT XVII AGAINST GLAND

Infringement of the '425 Patent Under § 271(e)(2) (ANDA No. 216965)

126. Paragraphs 1-125 are incorporated herein as set forth above.

127. Under 35 U.S.C. § 271(e)(2), Gland has infringed at least one claim of the '425 patent by submitting, or causing to be submitted to the FDA, ANDA No. 216965 seeking approval for the commercial marketing of Gland's proposed generic methylnaltrexone pre-filled syringe product before the expiration date of the '425 patent.

128. Upon information and belief, Gland's proposed generic methylnaltrexone pre-filled syringe product will, if approved and marketed, infringe at least one claim of the '425 patent.

129. Upon information and belief, Gland will, through the manufacture, use, import, offer for sale, and/or sale of Gland's proposed generic methylnaltrexone pre-filled syringe product, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '425 patent.

130. If Gland's marketing and sale of Gland's proposed generic methylnaltrexone pre-filled syringe product prior to the expiration of the '425 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

COUNT XVIII AGAINST GLAND

Declaratory Judgment of Infringement of the '425 Patent (ANDA No. 216965)

131. Paragraphs 1-130 are incorporated herein as set forth above.

132. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

133. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

134. Gland has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Gland's proposed generic methylnaltrexone pre-filled syringe product before the expiration date of the '425 patent, including Gland's filing of ANDA No. 216965.

135. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Gland's proposed generic methylnaltrexone pre-filled syringe product will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '425 patent.

136. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Gland's proposed generic methylnaltrexone pre-filled syringe product will constitute infringement of at least one claim of the '425 patent.

COUNT XIX AGAINST GLAND

Infringement of the '663 Patent Under § 271(e)(2) (ANDA No. 216965)

137. Paragraphs 1-136 are incorporated herein as set forth above.

138. Under 35 U.S.C. § 271(e)(2), Gland has infringed at least one claim of the '663 patent by submitting, or causing to be submitted to the FDA, ANDA No. 216965 seeking approval for the commercial marketing of Gland's proposed generic methylnaltrexone pre-filled syringe product before the expiration date of the '663 patent.

139. Upon information and belief, Gland's proposed generic methylnaltrexone pre-filled syringe product will, if approved and marketed, infringe at least one claim of the '663 patent.

140. Upon information and belief, Gland will, through the manufacture, use, import, offer for sale, and/or sale of Gland's proposed generic methylnaltrexone pre-filled syringe product, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '663 patent.

141. If Gland's marketing and sale of Gland's proposed generic methylnaltrexone pre-filled syringe product prior to the expiration of the '663 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

COUNT XX AGAINST GLAND

Declaratory Judgment of Infringement of the '663 Patent (ANDA No. 216965)

142. Paragraphs 1-141 are incorporated herein as set forth above.

143. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

144. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

145. Gland has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Gland's proposed generic methylnaltrexone pre-filled syringe product before the expiration date of the '663 patent, including Gland's filing of ANDA No. 216965.

146. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Gland's proposed generic methylnaltrexone pre-filled syringe product will

directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '663 patent.

147. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Gland's proposed generic methylnaltrexone pre-filled syringe product will constitute infringement of at least one claim of the '663 patent.

COUNT XXI AGAINST GLAND

Infringement of the '025 Patent Under § 271(e)(2) (ANDA No. 216965)

148. Paragraphs 1-147 are incorporated herein as set forth above.

149. Under 35 U.S.C. § 271(e)(2), Gland has infringed at least one claim of the '025 patent by submitting, or causing to be submitted to the FDA, ANDA No. 216965 seeking approval for the commercial marketing of Gland's proposed generic methylnaltrexone pre-filled syringe product before the expiration date of the '025 patent.

150. Upon information and belief, Gland's proposed generic methylnaltrexone pre-filled syringe product will, if approved and marketed, infringe at least one claim of the '025 patent.

151. Upon information and belief, Gland will, through the manufacture, use, import, offer for sale, and/or sale of Gland's proposed generic methylnaltrexone pre-filled syringe product, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '025 patent.

152. If Gland's marketing and sale of Gland's proposed generic methylnaltrexone pre-filled syringe product prior to the expiration of the '025 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

COUNT XXII AGAINST GLAND

Declaratory Judgment of Infringement of the '025 Patent (ANDA No. 216965)

153. Paragraphs 1-152 are incorporated herein as set forth above.

154. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

155. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

156. Gland has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Gland's proposed generic methylnaltrexone pre-filled syringe product before the expiration date of the '025 patent, including Gland's filing of ANDA No. 216965.

157. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Gland's proposed generic methylnaltrexone pre-filled syringe product will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '025 patent.

158. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Gland's proposed generic methylnaltrexone pre-filled syringe product will constitute infringement of at least one claim of the '025 patent.

COUNT XXIII AGAINST GLAND

Infringement of the '490 Patent Under § 271(e)(2) (ANDA No. 216965)

159. Paragraphs 1-158 are incorporated herein as set forth above.

160. Under 35 U.S.C. § 271(e)(2), Gland has infringed at least one claim of the ’490 patent by submitting, or causing to be submitted to the FDA, ANDA No. 216965 seeking approval for the commercial marketing of Gland’s proposed generic methylnaltrexone pre-filled syringe product before the expiration date of the ’490 patent.

161. Upon information and belief, Gland’s proposed generic methylnaltrexone pre-filled syringe product will, if approved and marketed, infringe at least one claim of the ’490 patent.

162. Upon information and belief, Gland will, through the manufacture, use, import, offer for sale, and/or sale of Gland’s proposed generic methylnaltrexone pre-filled syringe product, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the ’490 patent.

163. If Gland’s marketing and sale of Gland’s proposed generic methylnaltrexone pre-filled syringe product prior to the expiration of the ’490 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

COUNT XXIV AGAINST GLAND

Declaratory Judgment of Infringement of the ’490 Patent (ANDA No. 216965)

164. Paragraphs 1-163 are incorporated herein as set forth above.

165. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

166. There is an actual case or controversy such that the Court may entertain Plaintiffs’ request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

167. Gland has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Gland’s proposed generic

methylnaltrexone pre-filled syringe product before the expiration date of the ’490 patent, including Gland’s filing of ANDA No. 216965.

168. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Gland’s proposed generic methylnaltrexone pre-filled syringe product will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the ’490 patent.

169. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Gland’s proposed generic methylnaltrexone pre-filled syringe product will constitute infringement of at least one claim of the ’490 patent.

COUNT XXV AGAINST GLAND

Infringement of the ’125 Patent Under § 271(e)(2) (ANDA No. 216965)

170. Paragraphs 1-169 are incorporated herein as set forth above.

171. Under 35 U.S.C. § 271(e)(2), Gland has infringed at least one claim of the ’125 patent by submitting, or causing to be submitted to the FDA, ANDA No. 216965 seeking approval for the commercial marketing of Gland’s proposed generic methylnaltrexone pre-filled syringe product before the expiration date of the ’125 patent.

172. Upon information and belief, Gland’s proposed generic methylnaltrexone pre-filled syringe product will, if approved and marketed, infringe at least one claim of the ’125 patent.

173. Upon information and belief, Gland will, through the manufacture, use, import, offer for sale, and/or sale of Gland’s proposed generic methylnaltrexone pre-filled syringe product, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the ’125 patent.

174. If Gland's marketing and sale of Gland's proposed generic methylnaltrexone pre-filled syringe product prior to the expiration of the '125 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

COUNT XXVI AGAINST GLAND

Declaratory Judgment of Infringement of the '125 Patent (ANDA No. 216965)

175. Paragraphs 1-174 are incorporated herein as set forth above.

176. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

177. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

178. Gland has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Gland's proposed generic methylnaltrexone pre-filled syringe product before the expiration date of the '125 patent, including Gland's filing of ANDA No. 216965.

179. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Gland's proposed generic methylnaltrexone pre-filled syringe product will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '125 patent.

180. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Gland's proposed generic methylnaltrexone pre-filled syringe product will constitute infringement of at least one claim of the '125 patent.

COUNT XXVII AGAINST GLAND

Infringement of the ’445 Patent Under § 271(e)(2) (ANDA No. 216965)

181. Paragraphs 1-180 are incorporated herein as set forth above.

182. Under 35 U.S.C. § 271(e)(2), Gland has infringed at least one claim of the ’445 patent by submitting, or causing to be submitted to the FDA, ANDA No. 216965 seeking approval for the commercial marketing of Gland’s proposed generic methylnaltrexone pre-filled syringe product before the expiration date of the ’445 patent.

183. Upon information and belief, Gland’s proposed generic methylnaltrexone pre-filled syringe product will, if approved and marketed, infringe at least one claim of the ’445 patent.

184. Upon information and belief, Gland will, through the manufacture, use, import, offer for sale, and/or sale of Gland’s proposed generic methylnaltrexone pre-filled syringe product, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the ’445 patent.

185. If Gland’s marketing and sale of Gland’s proposed generic methylnaltrexone pre-filled syringe product prior to the expiration of the ’445 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

COUNT XXVIII AGAINST GLAND

Declaratory Judgment of Infringement of the ’445 Patent (ANDA No. 216965)

186. Paragraphs 1-185 are incorporated herein as set forth above.

187. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

188. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

189. Gland has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Gland's proposed generic methylnaltrexone pre-filled syringe product before the expiration date of the '445 patent, including Gland's filing of ANDA No. 216965.

190. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Gland's proposed generic methylnaltrexone pre-filled syringe product will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '445 patent.

191. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Gland's proposed generic methylnaltrexone pre-filled syringe product will constitute infringement of at least one claim of the '445 patent.

COUNT XXIX AGAINST GLAND

Infringement of the '096 Patent Under § 271(e)(2) (ANDA No. 216965)

192. Paragraphs 1-191 are incorporated herein as set forth above.

193. Under 35 U.S.C. § 271(e)(2), Gland has infringed at least one claim of the '096 patent by submitting, or causing to be submitted to the FDA, ANDA No. 216965 seeking approval for the commercial marketing of Gland's proposed generic methylnaltrexone pre-filled syringe product before the expiration date of the '096 patent.

194. Upon information and belief, Gland's proposed generic methylnaltrexone pre-filled syringe product will, if approved and marketed, infringe at least one claim of the '096 patent.

195. Upon information and belief, Gland will, through the manufacture, use, import, offer for sale, and/or sale of Gland's proposed generic methylnaltrexone pre-filled syringe product, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '096 patent.

196. If Gland's marketing and sale of Gland's proposed generic methylnaltrexone pre-filled syringe product prior to the expiration of the '096 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

COUNT XXX AGAINST GLAND

Declaratory Judgment of Infringement of the '096 Patent (ANDA No. 216965)

197. Paragraphs 1-196 are incorporated herein as set forth above.

198. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

199. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

200. Gland has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Gland's proposed generic methylnaltrexone pre-filled syringe product before the expiration date of the '096 patent, including Gland's filing of ANDA No. 216965.

201. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Gland's proposed generic methylnaltrexone pre-filled syringe product will

directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the ’096 patent.

202. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Gland’s proposed generic methylnaltrexone pre-filled syringe product will constitute infringement of at least one claim of the ’096 patent.

COUNT XXXI AGAINST GLAND

Infringement of the ’584 Patent Under § 271(e)(2) (ANDA No. 216965)

203. Paragraphs 1-202 are incorporated herein as set forth above.

204. Under 35 U.S.C. § 271(e)(2), Gland has infringed at least one claim of the ’584 patent by submitting, or causing to be submitted to the FDA, ANDA No. 216965 seeking approval for the commercial marketing of Gland’s proposed generic methylnaltrexone pre-filled syringe product before the expiration date of the ’584 patent.

205. Upon information and belief, Gland’s proposed generic methylnaltrexone pre-filled syringe product will, if approved and marketed, infringe at least one claim of the ’584 patent.

206. Upon information and belief, Gland will, through the manufacture, use, import, offer for sale, and/or sale of Gland’s proposed generic methylnaltrexone pre-filled syringe product, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the ’584 patent.

207. If Gland’s marketing and sale of Gland’s proposed generic methylnaltrexone pre-filled syringe product prior to the expiration of the ’584 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

COUNT XXXII AGAINST GLAND

Declaratory Judgment of Infringement of the ’584 Patent (ANDA No. 216965)

208. Paragraphs 1-207 are incorporated herein as set forth above.

209. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

210. There is an actual case or controversy such that the Court may entertain Plaintiffs’ request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

211. Gland has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Gland’s proposed generic methylnaltrexone pre-filled syringe product before the expiration date of the ’584 patent, including Gland’s filing of ANDA No. 216965.

212. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Gland’s proposed generic methylnaltrexone pre-filled syringe product will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the ’584 patent.

213. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Gland’s proposed generic methylnaltrexone pre-filled syringe product will constitute infringement of at least one claim of the ’584 patent.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment in their favor and against Gland on the patent infringement claims set forth above and respectfully request that this Court:

1. Enter judgment that, under 35 U.S.C. § 271(e)(2), Gland has infringed at least one claim of the '425 patent by submitting or causing to be submitted ANDA No. 216836 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Gland's proposed generic methylnaltrexone vial product before the expiration of the '425 patent;

2. Enter judgment that, under 35 U.S.C. § 271(e)(2), Gland has infringed at least one claim of the '425 patent by submitting or causing to be submitted ANDA No. 216965 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Gland's proposed generic methylnaltrexone pre-filled syringe product before the expiration of the '425 patent;

3. Enter judgment that, under 35 U.S.C. § 271(e)(2), Gland has infringed at least one claim of the '663 patent by submitting or causing to be submitted ANDA No. 216836 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Gland's proposed generic methylnaltrexone vial product before the expiration of the '663 patent;

4. Enter judgment that, under 35 U.S.C. § 271(e)(2), Gland has infringed at least one claim of the '663 patent by submitting or causing to be submitted ANDA No. 216965 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the

United States of Gland's proposed generic methylnaltrexone pre-filled syringe product before the expiration of the '663 patent;

5. Enter judgment that, under 35 U.S.C. § 271(e)(2), Gland has infringed at least one claim of the '025 patent by submitting or causing to be submitted ANDA No. 216836 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Gland's proposed generic methylnaltrexone vial product before the expiration of the '025 patent;

6. Enter judgment that, under 35 U.S.C. § 271(e)(2), Gland has infringed at least one claim of the '025 patent by submitting or causing to be submitted ANDA No. 216965 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Gland's proposed generic methylnaltrexone pre-filled syringe product before the expiration of the '025 patent;

7. Enter judgment that, under 35 U.S.C. § 271(e)(2), Gland has infringed at least one claim of the '490 patent by submitting or causing to be submitted ANDA No. 216836 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Gland's proposed generic methylnaltrexone vial product before the expiration of the '490 patent;

8. Enter judgment that, under 35 U.S.C. § 271(e)(2), Gland has infringed at least one claim of the '490 patent by submitting or causing to be submitted ANDA No. 216965 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Gland's proposed generic methylnaltrexone pre-filled syringe product before the expiration of the '490 patent;

9. Enter judgment that, under 35 U.S.C. § 271(e)(2), Gland has infringed at least one claim of the ’125 patent by submitting or causing to be submitted ANDA No. 216836 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Gland’s proposed generic methylnaltrexone vial product before the expiration of the ’125 patent;

10. Enter judgment that, under 35 U.S.C. § 271(e)(2), Gland has infringed at least one claim of the ’125 patent by submitting or causing to be submitted ANDA No. 216965 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Gland’s proposed generic methylnaltrexone pre-filled syringe product before the expiration of the ’125 patent;

11. Enter judgment that, under 35 U.S.C. § 271(e)(2), Gland has infringed at least one claim of the ’445 patent by submitting or causing to be submitted ANDA No. 216836 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Gland’s proposed generic methylnaltrexone vial product before the expiration of the ’445 patent;

12. Enter judgment that, under 35 U.S.C. § 271(e)(2), Gland has infringed at least one claim of the ’445 patent by submitting or causing to be submitted ANDA No. 216965 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Gland’s proposed generic methylnaltrexone pre-filled syringe product before the expiration of the ’445 patent;

13. Enter judgment that, under 35 U.S.C. § 271(e)(2), Gland has infringed at least one claim of the ’096 patent by submitting or causing to be submitted ANDA No. 216836 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the

United States of Gland's proposed generic methylnaltrexone vial product before the expiration of the '096 patent;

14. Enter judgment that, under 35 U.S.C. § 271(e)(2), Gland has infringed at least one claim of the '096 patent by submitting or causing to be submitted ANDA No. 216965 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Gland's proposed generic methylnaltrexone pre-filled syringe product before the expiration of the '096 patent;

15. Enter judgment that, under 35 U.S.C. § 271(e)(2), Gland has infringed at least one claim of the '584 patent by submitting or causing to be submitted ANDA No. 216836 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Gland's proposed generic methylnaltrexone vial product before the expiration of the '584 patent;

16. Enter judgment that, under 35 U.S.C. § 271(e)(2), Gland has infringed at least one claim of the '584 patent by submitting or causing to be submitted ANDA No. 216965 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Gland's proposed generic methylnaltrexone pre-filled syringe product before the expiration of the '584 patent;

17. Order that the effective date of any approval by the FDA of Gland's proposed generic methylnaltrexone vial product be a date that is not earlier than the expiration of the '425 patent, the '663 patent, the '025 patent, the '490 patent, the '125 patent, the '445 patent, the '096 patent, and the '584 patent, or such later date as the Court may determine;

18. Order that the effective date of any approval by the FDA of Gland's proposed generic methylnaltrexone pre-filled syringe product be a date that is not earlier than the expiration

of the ’425 patent, the ’663 patent, the ’025 patent, the ’490 patent, the ’125 patent, the ’445 patent, the ’096 patent, and the ’584 patent, or such later date as the Court may determine;

19. Enjoin Gland from the commercial manufacture, use, import, offer for sale, and/or sale of Gland’s proposed generic methylnaltrexone vial product until expiration of the ’425 patent, the ’663 patent, the ’025 patent, the ’490 patent, the ’125 patent, the ’445 patent, the ’096 patent, and the ’584 patent, or such later date as the Court may determine;

20. Enjoin Gland from the commercial manufacture, use, import, offer for sale, and/or sale of Gland’s proposed generic methylnaltrexone pre-filled syringe product until expiration of the ’425 patent, the ’663 patent, the ’025 patent, the ’490 patent, the ’125 patent, the ’445 patent, the ’096 patent, and the ’584 patent, or such later date as the Court may determine;

21. Enjoin Gland and all persons acting in concert with Gland from seeking, obtaining, or maintaining approval of Gland’s ANDA No. 216836 until expiration of the ’425 patent, the ’663 patent, the ’025 patent, the ’490 patent, the ’125 patent, the ’445 patent, the ’096 patent, and the ’584 patent;

22. Enjoin Gland and all persons acting in concert with Gland from seeking, obtaining, or maintaining approval of Gland’s ANDA No. 216965 until expiration of the ’425 patent, the ’663 patent, the ’025 patent, the ’490 patent, the ’125 patent, the ’445 patent, the ’096 patent, and the ’584 patent;

23. Declare this to be an exceptional case under 35 U.S.C. §§ 285 and 271(e)(4) and award Plaintiffs costs, expenses, and disbursements in this action, including reasonable attorney’s fees; and

24. Award Plaintiffs such further and additional relief as this Court deems just and proper.

Dated: February 22, 2022
Newark, New Jersey

Respectfully submitted,

s/ William P. Deni, Jr.

William P. Deni, Jr.
J. Brugh Lower
GIBBONS P.C.
One Gateway Center
Newark, New Jersey 07102
Tel: (973) 596-4500
Fax: (973) 596-0545
wdeni@gibbonslaw.com
jlower@gibbonslaw.com

Attorneys for Plaintiffs

Brian C. Diner
Justin Hasford
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, LLP
901 New York Avenue, NW
Washington, DC 20001
Tel: (202) 408-4000
Fax: (202) 408-4400

Attorneys for Plaintiffs Bausch Health Companies Inc., Salix Pharmaceuticals, Inc., and Progenics Pharmaceuticals, Inc.

CERTIFICATION OF NON-ARBITRABILITY PURSUANT TO LOCAL CIVIL RULE 201.1(d)

Pursuant to Local Civil Rule 201.1(d), the undersigned counsel hereby certifies that this action seeks declaratory and injunctive relief and, therefore, is not subject to mandatory arbitration.

I hereby certify under penalty of perjury that the foregoing is true and correct.

Dated: February 22, 2022
Newark, New Jersey

s/ William P. Deni, Jr.
William P. Deni, Jr.
GIBBONS P.C.
One Gateway Center
Newark, New Jersey 07102
Tel: (973) 596-4500
Fax: (973) 596-0545
wdeni@gibbonslaw.com

Attorney for Plaintiffs